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July 31, 2002

Commissioner for Patents  
Washington, D.C. 20231

Re: U.S. Patent Application No.: 10/031722  
For: HUMAN MONOCLONAL ANTIBODIES TO HER2/NEU  
Inventors: Tibor, Keler et al.  
Filed: January 18, 2002  
Our Ref. No.: MXI-160US

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Information Disclosure Statement;
2. PTO Form 1449;
3. Copies of references cited in PTO Form 1449 (51); and
4. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on:

July 31, 2002  
Date

Jane E. Remillard, Esq., Reg. No. 38,372

Respectfully submitted,  
LAHIVE & COCKFIELD, LLP

Jane E. Remillard, Esq.  
Attorney for Applicants  
Registration No. 38,872



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Keler, Tibor et al.

Serial No.: 10/031722

Filed: January 18, 2002

For: HUMAN MONOCLONAL ANTIBODIES TO  
HER2/NEU

Attorney Docket No.: MXI-160US

Group Art Unit:

Examiner:

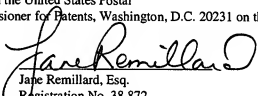
Commissioner for Patents  
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Certificate of First Class Mailing (37 CFR §1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on the date set forth below.

July 31, 2002  
Date of Signature and of Mail Deposit

By:

  
Jane Remillard, Esq.  
Registration No. 38,872  
Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT

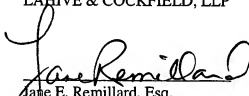
Dear Sir:

Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form 1449, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. A copy of each cited publication is enclosed.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR § 1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,  
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Date: July 31, 2002

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SERIAL NO.

MXI-160US

10/031722

 LIST OF PUBLICATIONS CITED BY APPLICANT  
 (Use several sheets if necessary)

APPLICANT

Tibor, Keler et al.

FILING DATE

January 18, 2002

GROUP

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
/ALH/	A1	4,753,894	06/88	Frankel et al.	436	548	
	A2	4,935,341	06/90	Bargmann et al.	435	6	
	A3	5,401,638	03/95	Carney et al.	435	7.23	
	A4	5,550,214	08/96	Eberlein et al.	530	328	
	A5	5,534,254	07/96	Huston et al.	424	135.1	
	A6	5,571,894	11/96	Wels et al.	530	387.3	
	A7	5,593,972	01/97	Weiner et al.	514	44	
	A8	5,604,107	02/97	Carney et al.	435	7.23	
	A9	5,677,171	10/97	Hudziak et al.	435	240.27	
	A10	5,705,157	01/98	Greene	424	138.1	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
/ALH/	A11	WO 90/14357 A1	11/90	PCT			
	A12	WO 91/02062 A2,A3	02/91	PCT			
	A13	WO 91/05264 A1	04/91	PCT			
	A14	WO 92/03918 A1	03/92	PCT			
	A15	WO 93/12220 A1	06/93	PCT			
	A16	WO 93/16185 A2	08/93	PCT			
	A17	WO 93/21232 A1	10/93	PCT			
	A18	WO 93/21319 A1	10/93	PCT			
	A19	WO 94/04679 A1	03/94	PCT			
	A20	WO 94/22478 A1	10/94	PCT			
	A21	WO 94/25585 A1	11/94	PCT			
	A22	EP 412116 B1	11/95	PCT			

## OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

/ALH/	A23	Baselga, J. et al. "Phase II Study of Weekly Intravenous Recombinant Humanized Anti-P185 <sup>HER2</sup> Monoclonal Antibody in Patients With HER2/ <i>neu</i> -Overexpressing Metastatic Breast Cancer" <i>Journal of Clinical Oncology</i> 14(3):737-744 (March 1996);
/ALH/	A24	Curnow, R.T. "Clinical experience with CD64-directed immunotherapy. An overview" <i>Cancer Immunology and Immunotherapy</i> 45(3/4):210-215 (November 1997);
/ALH/	A25	Jakovovits, A. "The long-awaited magic bullets: therapeutic human monoclonal antibodies from transgenic mice" <i>Expert Opinion on Investigational Drugs</i> 7(4):607-614 (April 1, 1998).
Examiner		Date Considered
/Anne Holleran/ (05/20/2008)		
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /ALH/

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 U.S. DEPARTMENT OF  
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## U.S. PATENT DOCUMENTS

EXAMINER NOTES		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	B1	5,720,937	02/98	Hudziak et al.	424	9.34	
	B2	5,720,954	02/98	Hudziak et al.	424	130.1	
	B3	5,725,856	03/98	Hudziak et al.	424	130.1	
	B4	5,726,023	03/98	Cheever et al.	435	7.1	
	B5	5,753,204	05/98	Huston et al.	424	1.49	
	B6	5,770,195	06/98	Hudziak et al.	424	130.1	
	B7	5,772,997	06/98	Hudziak et al.	424	130.1	
	B8	5,783,186	07/98	Arakawa et al.	424	143.1	
	B9	5,783,404	07/98	Koski	435	7.23	
	B10	5,801,005	09/98	Cheever et al.	435	7.24	
	B11	5,817,637	10/98	Weiner et al.	514	44	
	B12	5,821,337	10/98	Carter et al.	530	387.3	
	B13	5,824,311	10/98	Greene et al.	424	138.1	
	B14	5,830,876	11/98	Weiner et al.	514	44	
	B15	5,837,462	11/98	Beckers et al.	435	6	
	B16	5,837,846	11/98	Huston et al.	536	23.53	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
/ALH/	B17	WO 96/18409 A1	06/96	PCT				
	B18	WO 96/30514 A1	10/96	PCT				
	B19	WO 97/00271 A1	01/97	PCT				
	B20	EP 474727 B1	07/97	PCT				
	B21	WO 98/02463 A1	01/98	PCT				
	B22	WO 98/06863 A1	02/98	PCT				
	B23	WO 98/17797 A1	04/98	PCT				
	B24	WO 98/24884 A1	06/98	PCT				
	B25	EP 616812 B1	11/99	PCT				
	B26	WO 99/55367 A1	11/99	PCT				

## OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

Examiner	/Anne Holleran/ (05/20/2008)	Date Considered
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /ALH/